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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,709	10/24/2000	Lewis H. Lambert JR.	11016US05/100-236.P2.C2	3310

7590 08/13/2003

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[REDACTED] EXAMINER

SNEDDEN, SHERIDAN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1653

DATE MAILED: 08/13/2003

/2

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/696,709	LAMBERT, LEWIS H.
	<b>Examiner</b>	<b>Art Unit</b>
	Sheridan K Snedden	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 May 2003.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 12-14 is/are withdrawn from consideration.
- 5) Claim(s) 2 and 4 is/are allowed.
- 6) Claim(s) 1,3,9 and 11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

### ***Response to Amendment***

1. This Office Action is in response to Paper #9, filed 29 May 2003. Claim 10 has been canceled. Applicant's amendment of claim 1 is acknowledged. Claims 1-4, 9 and 11 are under examination.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 23 June 2003 was filed after the mailing date of the first Office action on the merits on 29 November 2002. The submission is in compliance with the provisions of 37 CFR 1.97(c). Accordingly, the information disclosure statement is being considered by the examiner.

### ***Withdrawal of Objections and Rejections***

3. All rejections not explicitly restated or stated below are withdrawn.

### ***Double Patenting***

4. Claims 1, 3, 9 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 5,955,427. Although the conflicting claims are not identical, they are not patentably distinct from each other because the products claimed are the same. The claims differ in that the claims of the instant application recite poloxamer 333, 334, 335 in addition to the shared poloxamer 403. However, the bactericidal-activity-enhancing poloxamer is obvious as Patent 5,955,427 teach poloxamer 403. As the poloxamer is identical in the conflicting claims, the bactericidal-activity-enhancing poloxamer is used in 5,955,427.

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5. Claims 1 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,488,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the products claimed are the same. The claims differ in that the instant application recites the use of the bactericidal-activity-enhancing poloxamer. However, the bactericidal-activity-enhancing poloxamer is taught in 5,488,034 and renders claims 1 and 9 obvious.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The applied references have a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

7. Claims 1, 3, 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by McGregor *et al.* (US Patent 5,955,427). McGregor *et al.* teach a pharmaceutical composition

comprising BPI and the stabilizing, bactericidal-activity-enhancing poloxamer 403. Thus, the reference anticipates the claimed invention.

8. Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by McGregor *et al.* (US Patent 5,488, 034). McGregor *et al.* teach a pharmaceutical composition comprising BPI and the stabilizing poloxamer. Example 1 teaches the use of poloamer 403 which is inherently a bactericidal-activity-enhancing poloxamer. Thus, the reference anticipates the claimed invention.

***Advisory Information***

9. Claims 2 and 4 are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
August 11, 2003

SKS

*Karen Cochrane Carlson, Ph.D.*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER